SMG 1121.80

FDA STAFF MANUAL GUIDES, VOLUME I – ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY

OFFICE OF REGULATORY AFFAIRS

OFFICE OF OPERATIONS

Effective Date: June 6, 2016

1. OFFICE OF OPERATIONS (DLLRI).

A. Provides direction and counsel to Regional Food and Drug Directors (RFDDs) in the implementation of policies and guidelines that form the framework for management of Agency global (domestic, U.S. border/port and international) operational activities.

B. Evaluates the overall management and capabilities of the Agency's field organization; initiates action to improve the management of global field activities.

C. Develops, issues, and approves proposals and instructions affecting global field activities. Develops, clears, issues and maintains guidance to the field in the Investigations Operations Manual.

D. Stimulates awareness within the Agency of the need for prompt and positive action to assure compliance by regulated industries; works to assure an effective and uniform balance between regulatory compliance and Agency responsiveness to consumer needs.

E. Resolves appeals when proposed compliance actions are disapproved by the Centers or the Office of the Chief Counsel.

F. Provides direction, assistance, management, and oversight of Agency import operations, including investigational and compliance activities. Serves as the Agency focal point for Headquarters/field relationships on all import programs, operations, and problems.

G. Provides strategic leadership and support for high quality, collaborative, scientific activities that advance regulatory science and address important

public health issues concerning FDA regulated products, including their evaluation, quality, safety and effectiveness.

H. Directs and coordinates ORA's emergency preparedness and response activities.

I. Participates, where appropriate, in international harmonization activities.

2. AUDIT STAFF (DLLRI1).

A. Conducts audits of domestic and international regulatory partners to measure their performance against program standards. Audits include reviews of regulatory systems and more specifically the inspection, investigation, sample collection and analysis, enforcement, response, recovery, and/or outreach components of these regulatory systems.

B. Coordinates with other ORA units on the development of training and certification programs for regulatory partners.

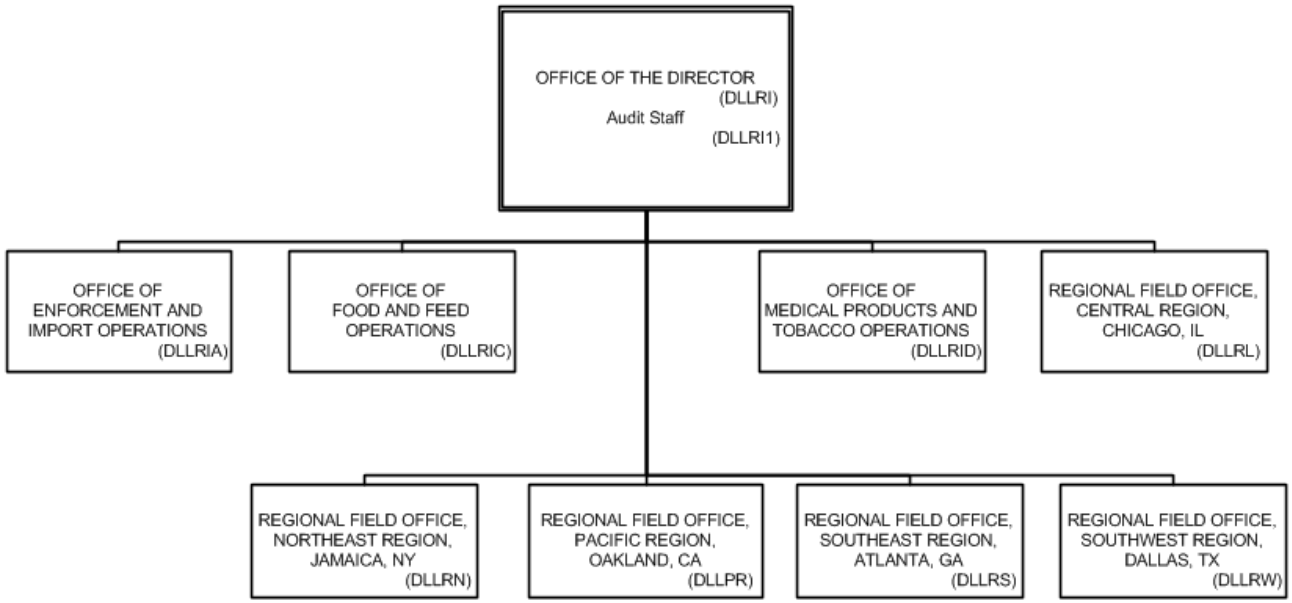
C. Develops program standards and associated audit programs that may apply to international and/or State regulatory partners and ORA.

D. Represents ORA and coordinates ORA participation on Agency workgroups responsible for comparability assessments and equivalence determinations of foreign regulatory partners.

3. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Secretary of Health and Humans Services and effective on June 6, 2016.

FOOD AND DRUG ADMINISTRATION
OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY
OFFICE OF REGULATORY AFFAIRS
OFFICE OF OPERATIONS



STAFF MANUAL GUIDE 1121.80
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: June 6, 2016

The following is the Food and Drug Administration, Office of Global Regulatory Operations and Policy, Office of Regulatory Affairs, Office of Operations organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DLLRI):

- Audit Staff (DLLRI1)

- OFFICE OF ENFORCEMENT AND IMPORT OPERATIONS (DLLRIA)
- OFFICE OF FOOD AND FEED OPERATIONS (DLLRIC)
- OFFICE OF MEDICAL PRODUCTS AND TOBACCO OPERATIONS (DLLRID)
- REGIONAL FIELD OFFICE, CENTRAL REGION, CHICAGO, IL (DLLRL)
- REGIONAL FIELD OFFICE, NORTHEAST REGION, JAMAICA, NY (DLLRN)
- REGIONAL FIELD OFFICE, PACIFIC REGION, OAKLAND, CA (DLLRP)
- REGIONAL FIELD OFFICE, SOUTHEAST REGION, ATLANTA, GA (DLLRS)
- REGIONAL FIELD OFFICE, SOUTHWEST REGION, DALLAS, TX (DLLRW)